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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,963	06/21/2005	Menachem Rubinstein	057878-16	3232

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EXAMINER
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MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,963	<b>Applicant(s)</b> RUBINSTEIN ET AL.	
	<b>Examiner</b> MARIA B. MARVICH	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 20-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-15, 17-19 and 34 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to an amendment filed. Claims 1-3, 5-32 and 34 are pending in the application.

#### ***Specification***

The disclosure is objected to because of the following informalities: On page 4, line 12, "I one aspect" should be amended to --In one aspect--.

In page 5, line 1, "bee.g." should be amended to --be e.g.--. In line 8, "and or" should be amended to --and/or--.

On page 6, line 7, 10 and 11, TNF $\alpha$  is abbreviated incorrectly and should be corrected.

Appropriate correction is required.

#### ***Claim Objections***

Claim 1, 2, 3 and 6 are objected to because of the following informalities: claim 1 is drawn to an isolated DNA sequence which "encodes a functional human IL-18BP promoter encoded by SEQ ID NO:1". This is incorrect as the sequence does not encode the promoter. It would be remedial to amend the claim to recite --sequence comprising a functional IL-18BP promoter which is SEQ ID NO:1--.

Furthermore, the claim recites "a functional human IL-18BP promoter activity containing fragment or a functional human IL-18BP activity containing derivative" which should for clarity, be amended to recite -- a functional IL-18BP promoter which is SEQ ID NO:1, fragment or

Art Unit: 1633

derivative thereof wherein the fragment or the derivative thereof comprises human IL-18BP activity and comprises SEQ ID NO:3--.

Finally, in claim 1, the phrase "wherein the 3' end of said DNA sequence or fragment thereof comprises one to 51 nucleotides from the 5' end of SEQ ID NO:5" requires clarification. As an initial point, the claim is not drawn to a fragment of the DNA sequence. Furthermore, it would be remedial to clarify the claim to recite, --wherein said DNA sequence comprises at the 3' end one to 51 nucleotides of the 5' end of SEQ ID NO:5--. The 3' end of the sequence can be anywhere within the 3' half of the molecule but the specification suggests that applicants intend the sequence to comprise at its 3' termini, the sequence from SEQ ID NO:5.

Claim 2 recites that "one or more AP1 sites present" in the sequence are mutated. For clarification it would be preferable that --SEQ ID NO:3-- replace "the sequence".

Claims 3 and 6 should be amended to recite --isolated DNA sequence--. Appropriate correction is required.

### ***Claim Construction***

Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997).

The instant claim 1 is directed to a DNA sequence encoding the functional IL-18BP promoter encoded by SEQ ID NO: 1, or a functional human IL-18BP promoter activity containing fragment or a functional human IL-18BP promoter activity containing derivative

Art Unit: 1633

thereof wherein the 3' end of said DNA sequence or fragment thereof comprises one to 51 nucleotides from the 5' end of SEQ ID NO: 5.

It is first noted that the claim is construed as directed to a nucleic acid or DNA molecule comprising a sequence encoding the functional IL-18BP promoter (or fragment or derivative).

The recitation "wherein the 3' end of said DNA sequence or fragment thereof comprises one to 51 nucleotides from the 5' end of SEQ ID NO: 5", according to its broadest reasonable scope, requires only that the portion of the claimed nucleic acid encoding the functional IL-18BP terminate with a cytosine (i.e., the 5' terminal nucleotide of SEQ ID NO: 5) at its 3' end.

Furthermore, as the application provides no specific definition of what constitutes the 3' end of a DNA sequence encoding a functional IL-18BP or fragment thereof, the claim is understood to read on any nucleic acid comprising a DNA sequence encoding an IL-18BP promoter activity containing fragment or derivative, wherein the nucleic acid also comprises a cytosine residue downstream of the promoter functional elements which can be arbitrarily identified as the 3' end of the sequence encoding the promoter. It is noted that the arbitrary designation of the 3' end is supported by dependent claim 3, which requires that the fragment comprise SEQ ID NO: 2. The 3' end of SEQ ID NO: 2 consists of the sequence "T-T", which does not appear anywhere in SEQ ID NO: 5. Therefore, the claims must read on molecules wherein the 5' cytosine of SEQ ID NO: 5 is arbitrarily upstream or downstream of the explicitly recited 3' end of the sequence.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1633

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-9 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by  
Entrez Nucleotide Database entry for Accession No. AF110798,  
<http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&id=4324923>, published 3 March  
1999, downloaded 29 October 2007 (hereinafter, the AF110798 sequence). **This rejection is  
maintained for reasons of record in the office action mailed 11/7/07 and restated below.**  
**Claim 34 has been added based upon applicants' amendment.**

The AF110798 sequence discloses an isolated nucleic acid comprising nucleotides 490-1272 of the instant SEQ ID NO: 1 (i.e., the sequence from 1 to 789 of the AF110798 sequence) and the entirety of the instant SEQ ID NO: 3 (662-782 of the AF110798 sequence), the GAS sequence at -24 to -32 relative to the transcriptional start site at 784 of the AF110798 sequence, the IRF-E sequence at -57 to -69 relative to the transcriptional start site and the C/EBP $\beta$  response elements at -309 to -322 and -621 to -634. If one arbitrarily identifies the "C" residue at base 784 as the 3' end of the DNA sequence encoding the promoter, the nucleic acid disclosed in the AF110798 sequence comprises all of the elements of the nucleic acid claimed in the instant claim 1. In addition, the AP1 sites present in the native IL-18BP nucleic acid are omitted from the AF110798 sequence which reads on a nucleic acid comprising a mutation (i.e., deletion) of the AP1 site according to claim 2 and the nucleic acid comprises SEQ ID NO: 2 according to claim 3 (*Id.*). The AF110798 sequence comprises the entire IL-18BP nucleic acid coding sequence and therefore comprises the intron of claims 5 and 6 and the operatively linked gene of claims 7 and 8. Finally, as described above, claim 9 does not specify the relative standard

Art Unit: 1633

for determining that an encoded protein is “heterologous”. As all proteins are heterologous to something, the naturally occurring IL-18BP gene also reads on the DNA sequence of claim 9.

Thus, the AF110798 sequence discloses a nucleic acid comprising all of the elements of the nucleic acid claimed in the instant application. Therefore, the claims are anticipated by the AF110798 sequence.

Claims 1, 3, 5-9, 12, 13 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Entrez Nucleotide Database entry for Accession No. AP000719, <http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=13094220>, sequence published prior to 23 July 2002 (see the attached revision history which shows no sequence modifications made after 23 July 2002), downloaded 28 October 2007 (hereinafter, the AP000719 sequence) as evidenced by Osoegawa et al. (2001) Genome Res. 11:483-496. **This rejection is maintained for reasons of record in the office action mailed 11/7/07 and restated below. Claim 34 has been added based upon applicants’ amendment.**

The AP000719 sequence discloses a nucleic acid comprising the entirety of the instant SEQ ID NO: 1 and SEQ ID NO: 2 (i.e., the sequence from 150907-152178). According to the description of the IL-18BP gene presented in the instant application (see, e.g., the final paragraph on page 9) this region of the AP000719 sequence would comprise all of the regulatory elements of the instant IL-18BP promoter. If one arbitrarily identifies the “C” residue at base 152179 as the 3’ end of the DNA sequence encoding the promoter, the nucleic acid disclosed in the AF110798 sequence comprises all of the elements of the nucleic acid claimed in the instant claim 1. With regard to claim 2, the AP1 sites identified in the instant application would be

Art Unit: 1633

present in the AP000719 sequence. However, the AP000719 sequence is viewed as reading on the claim because the application does not specify any structural or functional properties of a “mutant AP1 site” (e.g., the AP1 site comprises sequence A and does not bind AP1). As all nucleic acid sequences are the product of mutation and selection (natural or otherwise) the limitation “mutant AP1 site” reads on any sequence that is not an AP1 site or any AP1 sequence produced by a process of mutation (i.e., all AP1 sites).

The AP000719 sequence comprises the entire IL-18BP nucleic acid coding sequence and therefore comprises the intron of claims 5 and 6 and the operatively linked gene of claims 7 and 8. As described above, claim 9 does not specify the relative standard for determining that an encoded protein is “heterologous”. As all proteins are heterologous to something, the naturally occurring IL-18BP gene also reads on the DNA sequence of claim 9.

Finally, the AP000719 sequence entry teaches that the sequence is comprised in an RP11 clone (a.k.a., RPC-11; see under “DEFINITION”). Osoegawa et al. teaches that RPC-11 is a BAC library. (See especially page 492, second sentence of the “DISCUSSION”.) In view of the fact that nucleic acids in BAC libraries are comprised within vectors and propagated in bacteria, the vector of claim 12 and host cell of claim 13 are inherent to the teaching of the nucleic acid comprised in an RP11 clone as disclosed in the AP000719 sequence.

Thus, the AP000719 sequence as evidenced by Osoegawa et al. comprises all of the elements of the nucleic acid claimed in the instant application. Therefore, the claims are anticipated by the AP000719 sequence.

Claims 1, 3, 7, 9, 10, 12 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hurgin et al. (2001) *Journal of Interferon and Cytokine Research* 24:S. 73 (made of record in



the IDS filed 11 April 2005). **This rejection is maintained for reasons of record in the office action mailed 11/7/07 and restated below. Claim 34 has been added based upon applicants' amendment.**

Hurgin et al. teaches a 2 kb genomic sequence upstream of the human IL-18BP gene contains a promoter and enhancer element as determined by luciferase reporter vectors. Absent evidence to the contrary, one of skill in the art would conclude that the promoter sequences recited in the instant claims are inherent to the reporter vectors of Hurgin et al. in view of the fact that Hurgin et al. is characterizing the promoter region of the human IL-18BP gene (the sequence of which was known in the art at the time the instant application was filed (see, the AF110798 and AP000719 sequences *supra*). Therefore, the luciferase reporter constructs of Hurgin et al. anticipate the nucleic acid of claims 1-3, 7, 9 and 10 and the vector of claim 12.

#### ***Response to Argument***

Applicants' amendment has been persuasive in overcoming the rejection under Oda et al.

The remainder of applicants' arguments filed 5/6/08 have been fully considered but they are not persuasive. First, applicants argue that the database entries AF110798 and AP000719, while not mentioned it is presumed that reference AP000719 is intended to be included in this argument, do not identify the promoter region as such. However, this promoter region is part of an isolated sequence that comprises the recited sequences inherently. As to inherency, the properties need not be recognized as long as they are inherent. In fact, the MPEP teaches that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in

Art Unit: 1633

the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) (“[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.”); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) (“If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed function. Secondly, applicants argue that the entries do not include at least one nucleic acid from SEQ ID NO:5. However, the requirement of the claim is that it contain only one nucleic acid from SEQ ID NO:5, there is no structural or functional requirement of that nucleic acid. Hence, the addition of any nucleic acid to the 3' end of sequences 1 to 789 of the AF110798 or sequences 150907-152178 of AP000719 meets this requirement as each of A, G, C and T are represented in SEQ ID NO:5. Even should functional language be added to the claims, it is not clear that the addition of any random nucleic acid would not serve the same purpose of increasing the responsiveness of the promoter to IFN- $\gamma$ . As to Hurgin et al, applicants argue that amendment to recite that the fragment comprises SEQ ID NO:3 overcomes this rejection. However, for the reason that Hurgin et al is characterizing the ILB18bp promoter and as set forth by AF110798 and AP000719, this promoter is SEQ ID NO:1. The addition of any nucleic acid to the 3' end of the promoter meets

Art Unit: 1633

the requirements of the claims. Hence, as evidenced by AF110798 and AP000719 the promoter of Hurgin et al anticipates the instant claims. The rejection as anticipated by Hurgin et al was not based upon SEQ ID NO:3 but SEQ IDNO:1 that comprises SEQ IDNO:3.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurgin et al. (*supra*), as applied to claims 1 and 12 herein above, in view of Guan et al. (1995) *J. Biol. Chem.* 270:21958-21965. **This rejection is maintained for reasons of record in the office action mailed 11/7/07 and restated below.**

Claims 13-15 are directed to a host cell comprising the vector according to claim 12 (claim 13), wherein the host cell is a mammalian cell (claim 14) or a CHO cell (claim 15). The limitations of claims 1 and 12 and the teachings Hurgin et al. are described herein above. Although Hurgin et al. teaches that the promoter region of the human IL-18BP gene was characterized using a luciferase reporter vector, Hurgin et al. does not specify the cells used in the characterization method. Guan et al. teaches a method of characterizing a different human gene promoter using a luciferase reporter vector and teaches that CHO cells are a suitable host for such an assay. (See especially the paragraph bridging the left and right columns on page 21959, the paragraph bridging the left and right columns on page 21961, the first full paragraph in the right column on page 21961, Figure 5 and the caption thereto.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a CHO cell line to test the luciferase reporter vectors taught by Hurgin et al. In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized “the need for caution in granting a patent based on a combination of elements found in the prior art,” (*Id.* At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” (*Id.* At 1395.) In the

Art Unit: 1633

instant case, Hurgin et al. teaches the characterization of the human IL-18BP promoter using luciferase reporter plasmids and Guan et al. teaches that it was known in the art long before the instant application was filed that CHO cells are suitable host cells for testing luciferase reporter vectors. The only difference between the claimed invention and the prior art is the combination of elements known in the art. However, one of ordinary skill in the art could have combined the elements as claimed by known methods and, in that combination, each element would merely have performed the same function it did separately. As CHO cells were routinely used in the art for such assays, the results of combining the prior art elements would have been predictable to one of skill in the art at the time the invention was made.

Thus, all of the elements of claims were known to one of ordinary skill in the art at the time the invention was made and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of invention. Therefore, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 3, 5-13, 17-19 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurgin et al (above) in view of Novick et al (see 6,605,280, however, the rejection date is based upon WO 99/09063 which specification is the same). **This is a new rejection necessitated by applicants' amendment.**

The instant claims are drawn to a vector or isolated DNA comprising a gene encoding for example IL-18, a promoter for its expression and part of a viral genome.

The teachings of AF110798, AP000719 and Hurgin et al are as above. None of the references teaches expression of a gene e.g. IL-18 or that it is part of a viral genome.

Novick et al teach expression of IL-18bp under expression of a promoter in a recombinant AAV vector (see e.g. abstract and col 15, line 16-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the promoter construct detailed by Hurgin et al in the system of for example Novick et al . In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized “the need for caution in granting a patent based on a combination of elements found in the prior art,” (*Id.* At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on it precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” (*Id.* At 1395.) In the instant case, Novick et al. teaches an expression system with IL-18bp which can be placed under control of any effective promoter and reduces to practice an embodiment wherein it is placed in an aav vector with for example a CMV promoter and Hurgin et al teach that the IL-18bp promoter can be isolated and used to drive expression of a operably linked sequence. The only difference between the claimed invention and the prior art is the combination of elements known in the art. However, one of ordinary skill in the art could have combined the elements as claimed by known methods and, in that combination, each element would merely have performed the same function it did separately.

Thus, all of the elements of claims were known to one of ordinary skill in the art at the time the invention was made and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of invention. Therefore, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1633

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Primary Examiner  
Art Unit 1633

/Maria B Marvich/  
Primary Examiner, Art Unit 1633